calohii_20111107

CalOHII Notice of Proposed Regulations

Public comment closes at 5:00 PM, Monday November 7, 2011
These draft comments were developed by Redwood MedNet, a health data provisioning service located in Ukiah, California.
Version 3

Words which begin with capital letters are as defined in section 126010 of the proposed regulations.

DISCLAIMER
The following disclaimer is located on page 2 of Chapter 1:

"*DISCLOSURES REGARDING THE PROPOSED ACTION*
Adoption of these regulations will not:
(1) Create or eliminate jobs within California
(2) Create new businesses or eliminate existing businesses within California; or
(3) Affect the expansion of businesses currently doing business within California."

The finding of no impact by CalOHII is unsupported and unconvincing. Redwood MedNet believes that the proposed approach will impose unreasonable and unaffordable burdens on the field deployment of EHRs and health information exchange (HIE) services in California. The deployment of EHRs and HIE services does not occur in a simple, stable and homogenous market of interchangeable vendor contracts for mature and standardized products. On the contrary, California users work in a highly heterogeneous mix of legacy and next generation health information technology (IT) products, with a wide range of EHR vendor business models and product life cycles, and an emerging market of next generation mobile and cloud-based health IT services. Redwood MedNet believes that the proposed regulations, if not substantially changed after the demonstration period, will impose a chilling effect on HIE services. This negative impact may eliminate current California HIE services, may eliminate current California jobs, and may impede the expansion of HIE services in California.

126010 Definitions

Definitions in General
The revised definitions for terms commonly used to describe HIE services are now harmonized with the Federal definitions for the same terms. This is a substantial improvement over the previous unique definitions, which established a conspicuous conflict between State and Federal enforcement of widely divergent regulations governing the same HIE services.

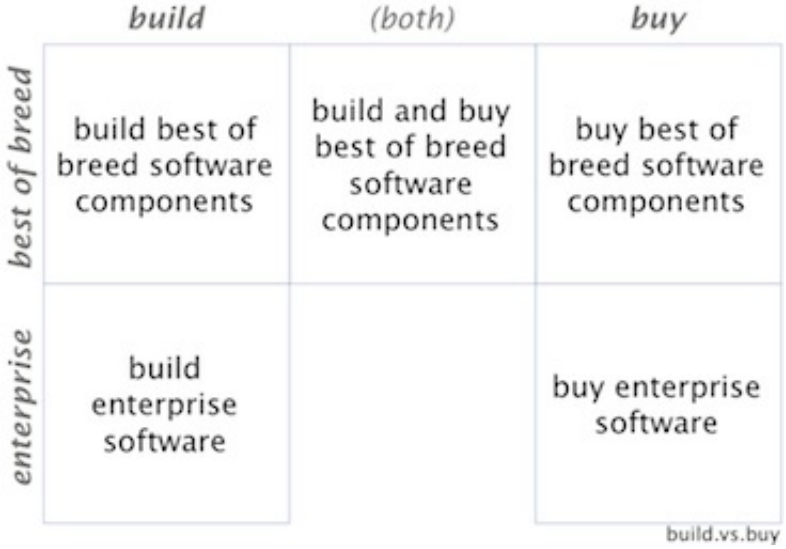
EHR Vendor Agreement
The new definition "EHR Vendor Agreement" should be deleted from the proposed regulations. The term serves no useful regulatory purpose and more importantly is likely to distract regulatory resources without improving the promotion and monitoring of clinical health data privacy and security. This is a "boil the ocean" approach to the

problem statement: "In the CalOHII stakeholder process, we have heard antidotal (sic) instances where EHR vendors may be seeing prolonged access or ownership over the individual health information..." ("Updated Informative Digest," p.7). If CalOHII "heard" anecdotal allegations about "prolonged access or ownership" of the data then the obvious place to start is with a targeted investigation to get to the bottom of the allegations rather than to archive and curate every EHR Vendor Agreement in existence. In this era of extreme budget limits it makes no sense for a California state agency to propose a resource intensive approach to a question that can be investigated with more focus on the problem and less of a wholesale fishing expedition. Rather than boil the ocean, focus the investigation and follow the allegations. The overbroad remedy ("A copy of the EHR Vendor agreement for each Participant." 126040 below) is a bureaucratic wild goose chase.

There are practical reasons why asking for all vendor agreements is an inefficient way answer the allegations.

Clearly the proposed regulation does not anticipate the complexity of software procurement. The proposed regulation defines EHR software procurement as a contract between "the participant and the primary organization that provided the participant with their EHR system." This definition presumes that EHR technology is purchased and deployed at a typical healthcare facility in California in the simple pattern of one EHR product purchased from one EHR vendor. However, this pattern of a simple and homogenous procurement contract for a mature and stable enterprise EHR software product will be frequently inaccurate due to many exceptions. In short, the proposed remedy ("A copy of the EHR Vendor agreement for each Participant.") is by definition incapable of targeting the wide breadth of EHR agreements. This is a critical blind spot in the proposed regulations. Compounding this error by contemplating remedies which seek to expand the definition of the EHR Vendor Agreement in order to more inclusively accumulate edge cases will distract rather than enhance State efforts to improve the privacy and security of clinical health data in EHR environments. The idea that close inspection of all EHR Vendor agreements will be a useful policy lever must be completely scrapped because such agreements inadequately define the real world of EHR deployments.

For every software deployment there are two independent variables: (1) build vs. buy; and (2) enterprise vs. best of breed. These two procurement variables are not limited to the deployment of EHRs, they are uniformly present in all software deployments. These variables lead to a 2 x 3 matrix.



The regulations proposed by CalOHII assume that all EHR acquisition is a simple purchase of a single enterprise EHR software package. While this is frequently true, it is not true in all cases.

- Many healthcare facilities utilize the "best-of-breed" approach by deployment of multiple individual software packages for health data; this is especially true at inpatient facilities (e.g., separate software packages for laboratory information, medication administration, narrative transcription, nursing notes, CPOE, etc.). This EHR procurement pattern is unanticipated by the proposed regulations.

- In the best-of-breed approach, a classic enterprise EHR product may be integrated in a hybrid fashion with other component software, such as a disease registry. This EHR procurement pattern is unanticipated by the proposed regulations.
- Some facilities write their own software, or write tools that perform specific best-of-breed functions in the clinical charting environment. This EHR procurement pattern is unanticipated by the proposed regulations.
- Many clinical professionals invent unique information tools, or use alternate clinical data protocols (for example, all the staff but one may use the facility's transcription service, while one provider opts to type their own notes on a computer). This EHR procurement pattern is unanticipated by the proposed regulations.
- The recent emergence of novel mobile health care apps with narrow feature sets offers many new options for EHR components; these may be deployed by staff in a rogue fashion, or may be approved for use on the local health facility network. This EHR procurement pattern is unanticipated by the proposed regulations.
- Although it might seem unlikely that a healthcare facility in California will build an enterprise software package, one Participant in the Redwood MedNet HIE services actually did write their own EHR from scratch [1]. Although an exception to the rule, this possibility is completely unanticipated by the proposed regulation.
- Some health care enterprises feature recently acquired or merged business units which utilize multiple separate EHR products in various stages of activation or decommissioning. Such enterprises tend to have multi-year lead times for migration from one complex legacy technology environment towards a planned future state featuring a (theoretically) less complex EHR environment. This EHR procurement pattern is unanticipated by the proposed regulations.
- ONC regulations for certification of EHRs explicitly allow the use of individual functional EHR components as an alternative to an enterprise EHR application. This EHR procurement pattern is unanticipated by the proposed regulations.

In short, many health IT installations in California involve multiple separate commercial EHR and technology service agreements with no guidance in the regulations for identification of the "primary" vendor agreement. In this regard, the proposed regulations as written will lead to regulatory enforcement chaos when applied to the heterogeneous field conditions of real EHR deployments in California because the regulations are silent on the large number of exceptions that do not match the regulatory expectations.

However, at a more basic level it is simply not relevant to focus on individual EHR Vendor Agreements. Acquiring and curating an archive of EHR Agreements agreements is needlessly complex and does not advance the regulatory mission of privacy and security oversight and enforcement. Chasing EHR Vendor Agreements does not fit the problem statement. It is better to focus on field inspection and monitoring of health IT services as actually deployed rather than to study the EHR contracts as negotiated and signed for the simple reason that the map is frequently divergent from the territory. In an era of limited resources, California's patients are better served by a regulatory focus on field deployments of EHRs and HIE services rather than on internal analysis of an infinite stream of shadow documents. The most recent high profile patient data privacy spill in California [2] typifies this point because the privacy spill was not from an EHR but rather was a secondary use data table posted on the Internet by a subcontractor in a routine internal business process. In short, the proposed focus on EHR Vendor Agreements represents a systemic misallocation of regulatory resources by asking the wrong question, and thereby creating an abstract analytic process which has little relevance to the practical protection of patient privacy in the real world.

Health Information Exchange

Deleting this definition is foolish. HIO is a noun. The verb function that is implied ("to exchange data") is pervasive in health care. The assumption that there is only "exchange" when an HIO is present is a mis-reading of the situation. This is really the heart of the problem: at a basic level the regulations do not address the actual health information exchange environment, but rather focus on an idealized world in which HIOs sign BAAs with CEs who each have an EHR Vendor agreement. The real world of electronic health data is so unlike the imaginary target universe of these regulations that the regulations amount to a game of whack-a-mole rather than a sober approach to the presence of

electronic data in a myriad of forms.

126040 Transparency and Complaint Process

This section conflates irrelevant regulatory requirements for Applicants and Participants and leaves no bright line distinctions to inform field deployment of either transparency or a complaint process. The Applicant for the Demonstration project is likely to be an HIO, which is by definition not a covered entity. Therefore the two sub-clauses (a)(1) and (a)(3) which refer to a Covered Entity will not apply to an HIO. For example, Redwood MedNet, a typical community-based HIO, coordinates no patient care and delivers no treatment services, and therefore does not trigger the Notice of Privacy Practices (NPP) requirement in 45 CFR 164.520. By extension, then, HIOs who are functionally similar to Redwood MedNet and who are Applicants in the CalOHII Demonstration project are also unlikely to trigger the NPP requirement. As non-patient-facing entities, such HIO Applicants also have no ready means of deploying the "complaint mechanism" described in clause 3. Thus it makes no sense that the "Applicant must provide CalOHII with copies of" patient facing documents (clause 1) or a patient facing complaint mechanisms or educational materials (clause 3) when the Applicant is likely to be a non-patient-facing enterprise with no natural means of producing such documents. Seeking to impose patient-facing reporting requirements on entities that have no patient-facing activities is unlikely to be a success.

Clause (b) applies not only to the Applicant, but also to all Participants in the Demonstration, and to all Business Associates of all Participants in the Demonstration. It is easy to understand how a forensic investigation into a privacy spill would seek access to such inter-organizational agreements. Redwood MedNet does not support this extreme appetite on the part of CalOHII for requesting, inspecting and curating so many business associate and HIE participation agreements. It is difficult to imagine that this clause may become a field level requirement for all health care entities in California for the simple reason that it is unlikely that CalOHII will have the administrative resources to demand, pursue and store such massive amounts of trivial administrative details.

Clauses (b), (c) & (d) appear to make the Applicant responsible for gathering and reporting every quarter an updated list of all Business Associates at all Participants. Further, CalOHII can demand copies of all Business Associate agreements within 5 working days. Applicant is also required to forward to CalOHII a copy of every "EHR Vendor Agreement" for all Participants. As noted above, this clerical busy work imposes a workflow penalty on Applicant staff, and gathers little content of regulatory value to CalOHII, assuming that CalOHII has sufficient staff to demand, pursue and store such massive amounts of content.

More specifically, the reporting requirements imposed by the regulations on a Covered Entity that may be a Participant in the Demonstration project creates a new set of costs and disincentives for Covered Entities to participate in the Demonstration project. This regulatory overburden is likely to dissuade some potential participants from joining the HIO Applicant during the Demonstration project, thereby materially harming the prompt expansion of HIE services and the drive for such HIOs to reach sustainability.

126050 Permitted Purposes for Exchanging Health Information

The narrow scope is in direct contrast to the new rules from HHS for patient access to their information. This oversight should be corrected.

126055 Informing Requirements; Affirmative Consent; Revocation of Consent

Redwood MedNet believes it is a mistake to seek to regulate only the initial electronic disclosure of patient health data,

and then to allow NPPs to govern the downstream re-distribution of the data. This uneven regulatory environment is typical of the failure of the proposed regulations to establish an environment of trust, or to appreciate the long-standing recommendations from the Federal Health IT Policy Committee.

126055 (b)(3)(A)(3) is will become a source of data error in health IT operations. Patients will be harmed. This is not an "if" situation, it is a "when" situation that only requires enough traffic for the first service failure to occur.

Why is revocation of consent alone considered? Why not also explicitly name the re-establishment of consent that was previously revoked?

Notes

1. OffSiteCare, a participant in the HIE services from Redwood MedNet, wrote their own EHR from scratch. www.offsitecare.com
2. Announcement in August of 300,000 records spilled from Stanford. http://www.mercurynews.com/health/ci_18728176